

JAN 30 2012

510(k) Summary¹

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Randy Byrd
VP, Chief Technical Officer
(978) 772-7070 x 272

Date of preparation of this summary: 20 December 2011

(2) Device trade or proprietary name: Glucose Meter-Check Solution for Infopia

Device common or usual name or classification name:

JJX Single (Specified) Analyte Control, All Types, Assayed and Unassayed

REGULATION MEDICAL SPECIALTY	REGULATION NUMBER	CLASS	REGULATION DESCRIPTION
Chemistry	862.1660	II	Glucose Control

I. Substantial Equivalence

Glucose Meter-Check Control Solution for Infopia is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use as shown in the following tables:

Characteristic	Predicate Device	Modified Device
Name:	Infopia Control Solution	Glucose Meter-Check Control Solution for Infopia
510(k), Date:	K0572369, Mar 21 2008	
Number of levels:	1, typical fasting glucose	1, typical fasting glucose
Target ranges:	94 – 140 mg/dL	88 – 132 mg/dL
Analytes:	glucose	glucose
Container:	6 mL LDPE vial with dispensing tip and cap	6 mL LDPE vial with dispensing tip and cap
Fill volume:	4 mL	4 mL
Color:	red	red
Matrix:	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.	Buffered, aqueous solution of D-Glucose, viscosity modifier, preservatives and other, non-reactive ingredients.
Brands:	Infopia	Glucose Meter-Check

¹ This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

II. Description of the new device

Glucose Meter-Check Solution for Infopia is a buffered aqueous solution with glucose containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation. The Glucose Meter-Check Solution is formulated for optimal performance on Infopia glucose meters using Infopia test strips.

(a) (1) Intended use of the device

Glucose Meter-Check Solution for Infopia is intended for use to verify the performance and correct operation of Infopia blood glucose monitoring test systems utilizing the Element family of blood glucose test strips. Glucose Meter-Check Solution for Infopia is intended for use by healthcare professionals and people with diabetes mellitus at home.

(a) (2) Technological characteristics of the device.

This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a single concentration of D-glucose with recovery on the test systems in the range corresponding to Interval 2 of the glucose concentration intervals for evaluation of intermediate precision in ISO 15197² (96 to 144 mg/dL). This solution has been optimized to simulate the response of whole blood on the blood glucose test systems manufactured by Infopia using Infopia blood glucose test strips. The solution contains no hazardous, human or animal derived components.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

- a) Closed bottle stability (Shelf-life)
- b) Stability after opening (Use-life)
- c) Transport Stability
- d) Test response

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

² ISO 15197. *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. 1st edition, May 2003.



Product Code	Class	Regulation	Device Name	Date Created

Registration and Listing

Premarket Reviews Completed (None)

Under Review, Withdrawn or Closed without Product Code (1)

K113764		GLUCOSE METER-CHECK SOLUTION FOR INFOPIA	Review	Claudio Olga
Image	FDA.GOV	JJK SINGLE ANALYTE CONTROL, ALL TYPES		K072369
K113764		GLUCOSE METER-CHECK SOLUTION FOR INFOPIA	Review	Claudio Olga
Image	FDA.GOV	JJK SINGLE ANALYTE CONTROL, ALL TYPES		K103021

MDR Summary (None)

MDR Analyst (None)

MDR Distribution by Brand - Death or Injury (None)

Patient Problems (None)

Patient Outcomes (None)

Device Problems (None)

Manufacturer Evaluation Results (None)

Manufacturer Evaluation Conclusions (None)

Recalls (None)

TPLC disclaimers

We are continuing to improve and enhance the TPLC Universe and the TPLC sheets. When more data is available we will update this message.

Please realize that in this initial release:

- Recall data is only available since October, 2009.
- In the Premarket Under Review section and the Recall section, the premarket submission or recall is only included if the product code is specified in CTS.
- The MDR count is a count of reports and contains duplicate reports.
- MDR track action or additional information letters is not available yet.
- EIR data related to inspections is not yet displayed.
- The TPLC name which consolidates variations on manufacturer names is not yet implemented.
- Publications are not yet linked in.

We are working hard to address these issues and many can be addressed before the next release.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JAN 30 2012

Bionostics, Inc.
c/o Randy Byrd
Chief Technical Officer
7 Jackson Road
Devens, MA 01434

Re: k113764
Trade/Device Name: Glucose Meter-Check® Solution for Infopia
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: December 20, 2011
Received: December 21, 2011

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Glucose Meter-Check® Solution for Infopia

Indications for Use: Glucose Meter-Check Solution for Infopia is intended for use to verify the performance and correct operation of Infopia blood glucose monitoring test systems utilizing Infopia glucose test strips. Glucose Meter-Check Solution for Infopia is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 1K113764

Page 1 of 1